FEB 1 2 2001

510(k) Summary

1. Sponsor/Manufacturing Information

Sponsor's Name: EDAP Technomed, Inc.

Contact Person: Scott J. Mindrebo, Vice President Regulatory Affairs

Address: 100 Pinnacle Way
Norcross, GA 30071

Telephone Number: 770-446-9950 ext. 214
Facsimile Number: 770-446-9951

Manufacturer's Name: Technomed Medical Systems SA

Contact Person: Philippe Scuiller, Vice President of Quality and Regulatory Affairs

Address: Parc d'Activites la Poudrette-Lamartine
4-6 rue du Dauphine
Vaulx-en-Velin, France 69120

Telephone Number: 011-33-4-72-15-31-50
Facsimile Number: 011-33-4-72-15-31-51

2. Proposed Device

Trade/Proprietary Name:	Sonolith Praktis
Common Name of Device:	Extracorporeal Shock Wave Lithotripter
CFR Number:	21 CFR 876.5990
Regulatory Class:	Class II (Special Controls)
Product Code:	78 LNS

Trade/Proprietary Name:	Endo Praktis Table
Common Name of Device:	Urology Table and Accessories
CFR Number:	21 CFR 876.4890
Regulatory Class:	Class II
Product Code:	MMZ

3. Predicate Device(s)

EDAP Technomed, Inc.'s SONOLITH 3000, marketed via PMA #P880011
Dornier Medizintechnik GmbH's MFL 5000, marketed via PMA # P840008/S024
Dornier Medizintechnik GmbH's HM3, marketed via PMA # P840008
Siemen's Modularis Uro Table, marketed via PMA# 870018

4. Device Description

The SONOLITH Praktis is a transmobile electroconductive shock wave lithotripter. It uses a patented electrode including a reservoir with a highly conductive solution. The shock wave generation consists of emitting an electrical discharge at the first focus (F1) of a truncated ellipsoid. The shock wave generated is bent back by the ellipsoid's inner wall to be precisely concentrated at the second focus (F2). The highly conductive liquid incorporated into the electrode guarantees a very high stability of the electrical arc at F1 ensuring very low dispersion at F2.

A special membrane mounted on the top of the generator ensures the acoustical coupling between the generator and the patient's skin. Moreover, the generator benefits from a real time pressure servo control device.

The Endo Praktis Table is the same table as the Modularis Uro Table that was FDA approved as part of the Siemens Modularis Uro lithotripter system but is privately labeled for EDAP Technomed.

5. Intended Use

The Sonolith Praktis is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

The Endo Praktis Table is intended for urological radiological diagnostics, endourological interventions (e.g. TURP), extracorporeal lithotripsy as well as prostate therapy (e.g. by means of microinvasive transurethral microwave therapy) in conjunction with the diagnostic and therapeutic modules of the platform.

6. Technological Characteristics

Shock Wave Characteristics are presented in the following table for minimum, typical, and maximum shock wave generator output settings. The hydrophone used to conduct the testing complies with FDA's 1991 SWL Guidance Document. The Shock Wave Characteristics, however, were measured using IEC 61846.

Acoustic Output Characteristics

			Min/Typical/Max
Peak-positive acoustic pressure (MPa)	▶		92/103/106 [1]
Peak-negative acoustic pressure (MPa)	▶		< 9 Mpa
Rise time (ns)	▶		42/52/52 ns [2]
Compressional pulse duration (ns)	▶		138/242/279 ns [2]
Maximum focal width (mm)	▶		1.6 [3]/3.2 [2]/3.6 mm
Orthogonal focal width (mm)	▶		1.4 [2]/2.7 [3]/3.6 mm
Focal extent (mm)	▶		12.8/21.1/25 mm [4]
Focal volume (mm3)	▶		15/94/173 [5]
Distance between the focus and target location (mm)	▶		0/1/7 mm [6]
Derived focal acoustic pulse energy (mJ)	▶		0.76/8/10.5 mJ [2]
Derived acoustic pulse energy at specified values of radius R (mJ)	▶	3 mm	4.7/19/22 mJ [2]
	▶	6 mm	7.1/36.8/48.8 mJ [2]

[1] PVDF hydrophone (Min : 1%(10 kV), Typ : 73%(14 kV), Max : 100 %(16 kV))
[2] Axis X values
[3] Axis Y values
[4] Axis Z values
[5] V = 4/3 .II . fx/2.fy/2.fz/2
[6] Focal shift on Z axis

7. Summary of Studies

The Sonolith Praktis conforms to the following consensus standards:

- IEC 601-1, (1988, 1991, 1995), "General Requirements for Safety."
- IEC 601-1-2, (first addition, 1993-04), "Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests (General)."
- IEC 60601-2-36, (1997), "Medical electrical equipment – Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy."
- IEC 61846, (1998), " Ultrasonics – Pressure pulse lithotripters – Characteristics of fields" with deviations.

The Sonolith Praktis was also tested and complies with the FDA's "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" issued on August 9, 2000.

8. Conclusion

The SONOLITH Praktis and the Endo Praktis Table are substantially equivalent to the predicate devices. The SONOLITH Praktis meets FDA's requirements set out in its "Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" issued on August 9, 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2001

Mr. Scott J. Mindrebo
Vice President, Regulatory Affairs
EDAP Technomed, Inc.
100 Pinnacle Way, Suite 100
NORCROSS GA 30071

Re: K003529
Sonolith Praktis, Endourology Praktis Table
Dated: November 15, 2000
Received: November 16, 2000
Regulatory Class: II
21 CFR §876.5990/Procode: 78 LNS
21 CFR§876.4890/Procode: 78 MMZ (Exempt)

Dear Mr. Mindrebo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K003529

Device Name: SONOLITH Praktis

Indications for Use: The Sonolith Praktis is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Device Name: Endo Praktis Table

The Endo Praktis Table is intended for urological radiological diagnostics, endourological interventions (e.g. TURP), extracorporeal lithotripsy as well as prostate therapy (e.g. by means of microinvasive transurethral microwave therapy) in conjunction with the diagnostic and therapeutic modules of the platform.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use _____ Over the Counter Use

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003529